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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/616,055

07/09/2003

Amarpreet S. Sawhney

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EXAMINER

PAK, JOHN D

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

03/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/616,055	<b>Applicant(s)</b> SAWHNEY, AMARPREET S.	
	<b>Examiner</b> John Pak	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 11, 20-22, 24, 25, 37-40 and 73-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 11, 20-22, 24, 25, 37-40 and 73-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1-5, 11, 20-22, 24-25, 37-40 and 73-77 are pending in this application.

This Office action is in response to applicant's amendments and remarks of 11/19/2008.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 11, 20-22, 24-25, 37-40 and 73-77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New matter, i.e. subject matter that does not find adequate descriptive support from the originally filed disclosure, is noted in the following claim language of independent claim 1, last three lines (emphasis added):

wherein the hydrogel, at the substantially less than equilibrium level of hydration, has a shape selected from the group consisting of a rod, a pellet, a bead sphere, a block, a sheet, a tube, irregularly shaped pieces, and a sheet rolled from one edge to another to form a roll, with the hydrogel having shape allowing for direct administration into a body by dimensions to passage through a catheter or hollow needle [[a tube]] having an inner diameter of no more than about 1.5 mm.

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It was already mentioned in the previous Office action that the only original disclosure of 1.5 mm is found on specification page 36, Example 12:

**Example 12**

**Use of a Hydrogel Plug to Close a Bronchial Fistula**

A hydrogel rod is formed as described in Example 8, except that the rod is formed in a mold 5 mm in diameter and has a 50 cm long suture embedded in it. The hydrogel is dried to a diameter of about 1.5 mm. The hydrogel may be placed in a catheter comprising a hollow flexible tube with a distal opening and a proximal end that remains outside the patient. The distal end may be maneuvered through the operating channel of a bronchoscope and into the bronchial tree to implant the hydrogel rod.

Thus, the entire sum of applicant's original disclosure as to 1.5 mm in any context at all is with respect to the diameter of a rod, not the inner diameter of a catheter or hollow needle. Example 12 would have conveyed to the skilled artisan in this field that the inner diameter of a catheter or hollow needle is likely to be greater than the rod diameter of 1.5 mm. Inner diameter of "no more than about 1.5 mm" was not conveyed because 1.5 mm rod diameter would have conveyed a larger inner diameter for a catheter or hollow needle, perhaps even much larger than 1.5 mm to account for possible longer length of the rod.

Applicant argues that tissue biopsy needles in use in this field **include** many needles that have an inner dimension of less than about 1.5 mm. However, even applicant's own submitted evidence shows that there are other biopsy needles that have

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larger inner dimensions, e.g. 14 gauge needles, and there is no clear-cut 1.5 mm dividing line (see below):

**Syringe Needle Gauge Chart**

Needle Gauge	Nominal O.D.			Nominal I.D.		
	mm	inches	tol./mm	mm	inches	tol./mm
10	3.404	0.1340	$\pm 0.0010$	2.692	0.1060	$\pm 0.0020$
11	3.048	0.1200	"	2.388	0.0940	"
12	2.769	0.1089	"	2.159	0.0850	"
13	2.413	0.0950	"	1.893	0.0746	"
14	2.108	0.0830	"	1.600	0.0630	"
15	1.929	0.0759	$\pm 0.0005$	1.372	0.0540	$\pm 0.0015$
16	1.851	0.0729	"	1.194	0.0470	"
17	1.473	0.0580	"	1.057	0.0416	"
18	1.270	0.0500	"	0.838	0.0330	"
19	1.067	0.0420	"	0.686	0.0270	"
20	0.902	0.0355	$\pm 0.0005$ $-0.0000$	0.584	0.0230	$\pm 0.0015$ $-0.0000$
21	0.813	0.0320	"	0.495	0.0195	"

There is no recognizable cutoff point that is 1.5 mm. 14 gauge is 1.6 mm and 15 gauge is 1.372 mm in inner dimension. Applicant has provided no evidence that one skilled in the art would have somehow arrived at an arbitrary inner diameter number like 1.5 mm when the two closest gauges do not provide that exact number. Therefore, given that available biopsy needles include those that have an inner diameter that is larger than 1.5 mm, the originally filed disclosure fails to adequately provide descriptive support for the newly added claim language as set forth above (last three lines of claim 1, as shown above).

For these reasons, all claims must be rejected again.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Johann Richter, can be reached on **(571)272-0646**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/John Pak/  
Primary Examiner, Art Unit 1616